



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

October 22, 2012

MEMORANDUM

TO: Lek Kadeli
Acting Assistant Administrator for Research and Development

FROM: Carolyn Copper /s/
Assistant Inspector General for Program Evaluation

SUBJECT: New Assignment Notification

The purpose of this memorandum is to notify you that the Office of Inspector General (OIG) plans to begin an evaluation of the Environmental Protection Agency's (EPA's) Research on Human Subjects. This assignment is in response to a Congressional request. Our objective is to determine whether EPA, as part of its research, followed applicable laws, regulations, policies, procedures, and guidance when it exposed human subjects to diesel exhaust emissions or concentrated airborne particles.

Specifically, in conducting the XCON, KINGCON, OMEGA CON, and any related studies exposing 41 human subjects to diesel exhaust emissions or concentrated air particles from 2010 to 2011, we plan to determine whether EPA:

- 1) Obtained sufficient approval to expose subjects to specific levels of diesel exhaust emissions or concentrated airborne particles;
- 2) Obtained adequate informed consent from human study subjects before exposing them to diesel exhaust emissions or concentrated airborne particles;
- 3) Adequately addressed any adverse events that occurred, including notifying the University of North Carolina at Chapel Hill's Institutional Review Board (IRB), the Human Studies Review Board, and the Human Subjects Research Review Official, revising consent forms as needed, and providing clinical follow-up in accordance with the approved protocol.

We plan to conduct work at EPA's Office of Research and Development (ORD), the Office of Science Advisor (OSA), the University of North Carolina at Chapel Hill, and other EPA offices and organizations, as appropriate. We will contact your audit liaison to arrange a mutually agreeable time for an entrance conference to discuss our assignment plans. We will also answer any questions about the evaluation process and reporting procedures. If you or your staff have any questions about this assignment, please contact Rick Beusse, Director for Program Evaluation, Air & Research Issues, at (919)541-5747 or beusse.rick@epa.gov, or Renee McGhee-Lenart, Project Manager, at (913)551-7534 or mcghee-lenart.renee@epa.gov.

cc: Robert Kavlock, Deputy Assistant Administrator for Science, ORD
Ramona Trovato, Acting Principal Deputy Assistant Administrator for Management, ORD
Harold Zenick, Director, National Health and Environmental Effects Research
Laboratory (NHEERL), ORD
Chris Robbins, Acting Deputy Director, NHEERL, ORD
Wayne Cascio, Director, Environmental Public Health Division, NHEERL, ORD
Glenn Paulson, Science Advisor to EPA
Jim Downing, Executive Director, Human Studies Review Board, OSA
Rebecca Tyrrell Parkin, Chair, Human Studies Review Board, OSA
Warren Lux, Human Subjects Research Review Official, OSA
Hyon Kim, Audit Follow-up Coordinator, ORD
Norman Adkins, Audit Follow-up Coordinator, ORD
Arthur A. Elkins, Jr., Inspector General
Charles Sheehan, Deputy Inspector General
Alan Larsen, Counsel to the Inspector General
Melissa Heist, Assistant Inspector General for Audit, OIG
Patricia Hill, Assistant Inspector General for Mission Systems, OIG
Patrick Sullivan, Assistant Inspector General for Investigations, OIG
Eileen McMahon, Assistant Inspector General for Congressional and Public Affairs, OIG
Jeffrey Harris, Acting Deputy Assistant Inspector General for Program Evaluation, OIG
Rick Beusse, Director for Program Evaluation, Air & Research Issues, OIG
Renee McGhee-Lenart, Project Manager, Air & Research Issues, OIG